UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,003	03/14/2005	Daniel S. Martin	636-C-PCT-US	6708

57545 7590 04/04/2008

LAW OFFICES OF ALBERT WAI-KIT CHAN, PLLC
141-07 20TH AVENUE, SUITE 604
WORLD PLAZA
WHITESTONE, NY 11357

EXAMINER	
CRANE, LAWRENCE E	
ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
04/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,003	MARTIN ET AL.	
	Examiner	Art Unit	
	Lawrence E. Crane	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *October 2, 2007 (RCE & amdt)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54,55,59-62 and 65-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54,55,59-62 and 65-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/07; 10/07;12/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims **1, 17-20, 22-45 and 50-53** were previously cancelled, claims **2-16, 21, 46-49, 56-58 and 63-64** have been cancelled, claims **48-49** have been amended, the disclosure has been amended at page 1, and new claims **65-70** have been added as per the amendment filed June 1, 2007 and entered October 10, 2007 following the Request for Continued Examination (RCE) filed October 2, 2007. Three additional or supplemental Information Disclosure Statements (3 IDSs) filed on May 11, 2007, October 29, 2007 and December 21, 2007 have been received with all cited on-US patent references and made of record. Examiner also notes that applicant has supplied a Terminal Disclaimer, a disclaimer that has been reviewed, found acceptable, made of record, and which has rendered moot the previous rejection alleging obvious double patenting.

Claims **54-55, 59-62 and 65-70** remain in the case.

Claims **54, 60-62 and 65-70** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The fundamental issue here is whether practicing the full scope of the instant invention is possible without undue experimentation. As provided for in In re Wands (858 F.2d 731, 737; 8 USPQ 2d 1400, 1404 (Fed Cir. 1988) the minimum factors to be considered in determination of whether a conclusion of "undue experimentation" is appropriate are as follows:

A + B. The breadth of the claims and the nature of the invention: The invention claimed is directed to the administration of the five ingredients listed in claim **65**, and the multiple ingredients listed in claim **67**, with the optional additional administration of one or two additional ingredients listed in claims **66 and 68-70** to effectively treat breast cancer, ovarian cancer, or pancreatic cancer.

C. The state of the prior art: The prior art does not appear to disclose the administration of the combination of the listed ingredients in claims **65 and 67** or those ingredients plus the ingredients additionally listed in claim **66** or claims **68-70**, or the pharmaceutical compositions defined by claimed **54 and 61-62**.

D. The level of one of ordinary skill: The ordinary practitioner would be expected to be knowledgeable in the practice of both medical chemotherapy and associated neoplastic cell biochemistry.

E. The level of predictability in the art: The predictability of the treatment of neoplastic disease conditions is remains low because the understanding of how and/or why a method is effective, or ineffective, in the treatment of the manifold different diseases encompassed by the term "neoplastic" remains incomplete. This view continues to apply to the listed disease conditions, and particularly to pancreatic cancer, a disease typically characterized by a very short life expectancy following diagnosis.

F. The amount of direction provided by the inventor: The instant disclosure provides limited guidance concerning the anti-neoplastic effects of the methodology encompassed by claim **67 and 68**, but appears to only speculate concerning the likelihood of success in re administration of the mixtures of ingredients listed in claims **65, 66 and 69-70**.

G. The existence of working examples is limited to breast cancer, sarcomas, leukemia and transplanted breast cancers and in no case noticed by examiner was either **DHEA , OT or "F16"** included in an executed test protocol. If this is not the case, examiner would appreciate guidance concerning the location(s) of data in the disclosure that enables the inventions encompassed by claims **65, 66 and 69-70**.

H. The quantity of experimentation needed to use the invention based on the content of the disclosure is deemed to be undue because applicant apparently has not disclosed sufficient test data to fully enable the effective administration of that any one of the claimed combinations of active ingredients listed in claims **65-70** as an effective treatment of any living host, or any appropriate cell test culture, wherein a breast cancer, an ovarian cancer or a pancreatic cancer is present. The above rejection also applies to the pharmaceutical composition claims **54 and 60-62** because only a prospective disclosure supporting the administration of "F16" containing pharmaceutical compositions is present at the end of the instant specification.

Applicant's arguments with respect to claims **54, 60-62, 65, 66 and 69-70** have been considered but are moot in view of the new grounds of rejection. This new ground of rejection was necessitated by applicant's introduction of new claims.

Claims **58, 59, 68 and 69** are objected to because of the following informalities:

In claims **58, 59, 68 and 69**, the term "Adriamycin" is improperly capitalized.

Appropriate correction is required.

Claims **66 and 68-70** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims **66 and 68-70**, the term "comprising" should be followed by the term "administration of" in order to make the claim complete in view of the subject matter of the relevant independent claims both of which are method of treating claims wherein the "administration" of a cocktail of drugs is the encompassed subject matter.

Applicant's arguments with respect to claims **66 and 68-70** have been considered but are moot in view of the new grounds of rejection. This new ground of rejection was necessitated by applicant's introduction of new claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

"A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

Claims **55 and 59** are rejected under 35 U.S.C. §102**(b)** as being anticipated by **Nord et al.** (PTO-1449 ref. **#11**).

Applicant is referred to page 380, Table 3 (explanation at the top of the table) and associated explanatory text.

Applicant's arguments filed June 1, 2007 have been fully considered but they are not persuasive.

Applicant is referred to **Nord et al.** at p. 376, column 2, last last paragraph, wherein the noted reference discloses the instant combination of active ingredients as claimed separately or in combination with adriamycin as active in the treatment of neoplasms.

Claims **55 and 59** are rejected under 35 U.S.C. §102(**b**) as being anticipated by **Stolfi et al.** (PTO-1449 ref. **R**).

Applicant is referred to the Abstract wherein adriamycin and the remaining active ingredients are disclosed as an effective pharmaceutical composition.

Applicant's arguments filed June 1, 2007 have been fully considered but they are not persuasive.

Applicant's arguments are very brief and conclusory and therefore do not provide a basis for rebuttal.

For equivalent references see **Colifiori et al.** (PTO-892 ref. **S**); **Martin et al.** (PTO-892 ref. **T**); and **Koutcher et al.** (PTO-892 ref. **U**).

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571,273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

LECrane:lec
03/31/2007

/Lawrence E. Crane/

Examiner, Art Unit 1623

L. E. Crane, Ph.D., Esq.
Patent Examiner
Technology Center 1600